

Appl. No. 09/784,665  
Amtdt.AF dated February 11, 2005  
Reply to Final Office Action of December 13, 2004

### REMARKS

Applicants have carefully reviewed the Final Office Action mailed on December 13, 2004. Applicants respectfully traverse all objections, rejections, and assertions made by the Examiner. Claims 1-21 remain pending.

Claims 1-21 are rejected under 35 U.S.C. §103(a) as being unpatentable over McIntyre et al. in U.S. Patent No. 5,334,153 in view of Gabel et al. in U.S. Patent No. 4,759,751. The Examiner indicated that Applicants previous remarks were unpersuasive because the Examiner believes that the McIntyre et al. seal is releasable and that combining Gabel et al. with McIntyre would not render the catheter useless. We do not concede the merits of the Examiner's statements and respectfully re-assert that it is not proper to combine the cited references for at least the reasons stated below.

The seal system of McIntyre et al. is made up of two separate gaskets 26, 28. The first, gasket 26, "provides an air-tight seal on the inner tubular member 2". McIntyre et al. at column 5, lines 53-56. Gasket 26 is "constantly present to prevent leakage of air into lumen 5". McIntyre et al. at column 6, lines 44-48. The second, gasket 28, is compressible onto inner tubular member 2 by rotating cap 24 onto housing 21. Please see McIntyre et al. at column 6, lines 28-39.

Independent claims 1 and 9 each recite a pierceable seal releasably attached to the first port. Independent claim 16 similarly recites a method step of providing a catheter having this type of seal. By virtue of being releasably attached to the first port, the seal can function by sealing the first lumen (e.g., inflation lumen) during an evacuation procedure where air and/or fluids are removed from the balloon. Importantly, because the seal is releasably attached to the first port, a clinician can easily gain access to the seal and remove it at the appropriate time during an intravascular intervention. As described above, gasket 26 is "constantly present". This express statement from McIntyre et al. teaches away from gasket 26 being releasably attached to the first port.

Please also observe that gasket 26 is disposed deeply within housing 21. One can readily ascertain that in order for it to be practical for gasket 26 to be releasably attached to the first port, it should be possible for a clinician to release it from the first port. Because of the position of the gasket 26 within the housing and the small size of housing 21, it simply does not make sense that

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the design of the McIntrye et al. device would contemplate having a clinician reach deep inside a miniscule housing 21 in order to remove gasket 26. Instead, Applicants respectfully submit that only two interpretations are plausible to explain the relationship of gaskets 26/28 with housing 21. One is that the gasket 26 is fixed to housing 21. This makes the most sense given that the purpose of gasket 26 is to "constantly" seal against inner tubular member 2. Alternatively, seal 26 could be loosely disposed within housing 21. This is apparently what the Examiner is asserting is possible. Whether or not this configuration is, in fact, disclosed, it fails to meet the limitations of claims 1, 9 and 16 because the gasket 26 would not be attached to the first port. Indeed under this interpretation, gasket 26 would not be attached (releasably or otherwise) to anything. Therefore, gasket 26, under either scenario, cannot meet the limitations of claims 1, 9, and 16.

The McIntrye et al. gasket 28 similarly fails to meet claims 1, 9, and 16. As described above, gasket 28 can be compressed down onto inner tubular member 2. Therefore, gasket 28 is only releasable from inner tubular member 2 and not the first port. However, it would seem impractical for gasket 28 to also be releasable from housing 21. Again, the sheer size of housing 21 (making it difficult for the clinician to get their fingers within the housing) and the positioning of gasket 28 within housing 21 teaches away from a releasable attachment due to the fact that it would be impractical to release it from the housing. Only the two types of attachments described above (i.e., non-releasably attached to housing 21 or not attached to housing 21 at all) are plausible. For the reasons stated above, both of these interpretations fail to suggest that gasket 28 is releasably attached to the housing. Therefore, gasket 28 cannot meet the limitations of claims 1, 9, and 16.

The claimed seal is also pierceable. The Examiner indicated that Gabel et al. disclose a pierceable seal and that it would be proper to combine the references in order to arrive at the claimed invention. We disagree. MPEP §2143.01 states that "[t]here are three possible sources for a motivation to combine references: the nature of the problem solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." MPEP §2143.01 citing In re Rouffet, 149 F. 3d 1350, 1357 (Fed. Cir. 1998). McIntrye et al. go to great lengths to describe the intricacies of their complex sealing system and how it works during the use of their disclosed purging system. The disclosure regarding the gaskets, therefore, is highly suggestive of the

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permanence contemplated for the sealed portion of the catheter. After describing the gaskets, McIntyre et al. go on to disclose that a fitting 25 is coupled to the side leg 22 of the housing 21. McIntyre et al. at column 6, lines 51-54. "The fitting 25 is designed to receive a syringe or the like so that air may be purged from the lumen 5 and the balloon 8." McIntyre et al. at column 6, lines 54-56. This indicates that the only way that air may be purged from the system is to attach a syringe to the side leg. Nothing suggests the desirability of purging the system through the gaskets, which are expressly disclosed as being "constant" or permanently sealed. The disclosure of attaching a syringe to the side leg thus explicitly teaches away from utilizing a pierceable seal. Therefore, there is no reasonable motivation to combine the teachings of Gabel et al. with McIntyre et al. in order to arrive at the claimed invention.

It is worth noting that the Gabel et al. patent issued prior to the filing of the McIntyre et al. patent. Therefore, at the time of filing the McIntyre et al., Gabel et al. was publicly available. Even though so-called "piercable seals" were available at the time of filing (via Gabel et al.), McIntyre et al. chose a completely different strategy for purging their catheter system. This strongly suggests that even if it was possible to combine the teachings of Gabel et al. with McIntyre et al., McIntyre et al. decided that an altogether different strategy was much more favorable. This further demonstrates the lack of motivation to combine Gabel et al. with McIntyre et al. Accordingly, combining McIntyre et al. with Gabel et al. amounts to nothing more than reconstructive hindsight.

In light of the foregoing comments, Applicants respectfully submit that a rejection of the pending claims under 35 U.S.C. §103(a) in view of the combination of McIntyre et al. and Gabel et al. is not proper. Therefore, claims 1-21 are believed to be in condition for allowance.

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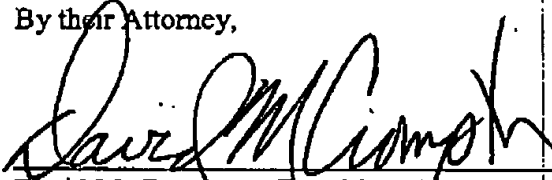
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Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

Date: 2/11/05

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